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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,405	01/26/2001	Geralt Williams	PX3904 USW	8052

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EXAMINER

BRINSON, PATRICK F

ART UNIT	PAPER NUMBER
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3754

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/647,405	Applicant(s) WILLIAMS, GERALT	
	Examiner Patrick F. Brinson	Art Unit 3754	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 10-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 10-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/2/05</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 10-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,596,260 to **Brugger et al.** in view of U.S. 6,149,892 to **Britto**.

The patent to **Brugger et al.** discloses a metering valve assembly for dispensing a pharmaceutical product comprising a valve stem (21) having a dispensing channel (22) adapted to receive and expel a predetermined volume of the pharmaceutical product when the valve stem is actuated. A valve body (25) having a metering chamber (20), wherein the metering chamber includes at least one chamber wall, wherein the metering chamber is in communication with the dispensing channel during the actuation of the valve stem. The metering chamber is adapted to receive a first volume of the pharmaceutical product at a first time, dispense the first volume during a first actuation of the valve stem and receive a second volume of the product through slot (26) at a second time and dispense the second volume during a second actuation of the valve stem. The valve device includes chamber seals (250, 251) in

communication with the valve stem and a spring (F). The reference goes on to disclose that the container is provided with a coating of plastic, preferably a coating of polytetrafluoroethylene, also known as Teflon®, or of perfluoroethylenepropylene. The use of these materials prevents significant deposits of the active substance on the inner wall of the container. **Brugger et al.** does not disclose the metering chamber nor the dispensing channel including a material that would prevent the materials from sticking thereto and therefore prevent proper actuation of the valve. The patent to **Britto** discloses a metered dose inhaler having all or part of its internal surfaces coated with one or more fluorocarbon polymer. Col. 2, lines 1-6, states that metered dose inhaler or MDI means a unit comprising a can, a crimped cap coving the mouth of the can, and a drug metering valve situated within the cap. Lines 9-16 disclose that the valve refers to a valve and its associated mechanisms that deliver a predetermined amount of drug formulation from an MDI upon each activation. Col. 4, states that the drug metering valve consist of parts usually made of stainless steel, a pharmacologically inert and propellant resistant polymer, such as fluorocarbon polymer, like Teflon®. Col. 6 further disclose that MDI's taught in the reference are particularly useful for containing and dispensing inhaled drug formulations with hydrofluoroalkane fluorocarbon propellants with little or essentially no, excipient and which tend to deposit or cling to the interior walls and parts of the MDI system. It would have been obvious to one having ordinary skill in the art at the time the

invention was made to modify any of the metering valve parts, or coat the parts of the metering valve assembly, in particular the walls of the metering chamber and/or the dispensing channel with a fluorinated polymer, such as polytetrafluoroethylene, as suggested by **Britto** in order to provide a metering valve that will allow for consistent expelling of medication and which will dispense substantially equal volumes of pharmaceutical product with each actuation of the valve stem.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Patrick F. Brinson** whose telephone number is (571) 272-4897. The examiner can normally be reached on M-F 7:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Michael Y. Mar** can be reached on (571) 272-4906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, reading "Patrick F. Brinson". The signature is written in a cursive, flowing style with a large initial "P".

Patrick F. Brinson  
Primary Examiner  
Art Unit 3754

P. F. Brinson  
March 20, 2006